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Docket No.: OSTEONICS 3.0-408
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Delogé et al.

Application No.: 10/008,336

Group Art Unit: 3732

Filed: November 8, 2001

Examiner: Not Yet Assigned

For: TARGETING APPARATUS FOR USE IN PERFORMING ENDOFEMORAL OSTEOTOMY SURGERY

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicant hereby claims priority under 35 U.S.C. 119 based on the following prior foreign applications filed in the following foreign countries on the dates indicated:

Country	Application No.	Date
Great Britain	GB-A-01 24230.4	October 9, 2001
Great Britain	GB-A-00 27698.0	November 13, 2000
Great Britain	GB-A-00 27700.4	November 13, 2000
Great Britain	GB-A-01 05779.3	

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date shown below.

Dated: April 15, 2002 Signature: _____
(Raymond W. Augustin)

363537_1.DOC

In support of this claim, certified copies of the original foreign applications are filed herewith.

Dated: April 15, 2002

Respectfully submitted,

By _____
Raymond W. Augustin
Registration No.: 28,588
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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Signed Andrew Gerrard

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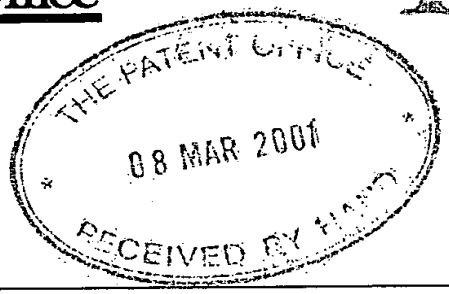

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1. Your reference

AJBB/SPY/H.103

09MAR01 E612246-1 D02624
1/7700 0.00-0105779.3

2. Patent application number
(The Patent Office will fill in this part)

0105779.3

8 MAR 2001

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BENOIST GIRARD SAS
203, Boulevard de la Grande Delle - B.P.8.
14201 Hérouville-Saint-Clair Cédex,
France.

Patents ADP number *(if you know it)*

8098337001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

APPARATUS FOR USE IN PERFORMING TRANSFEMORAL OSTEOTOMY

5. Name of your agent *(if you have one)*

A.J. BRIDGE-BUTLER

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

G.F. REDFERN & CO.
7 Staple Inn,
Holborn,
London WC1V 7QF

Patents ADP number *(if you know it)*

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6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

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Claim(s)	
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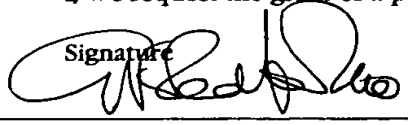
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature 

Date 8 March 2001

12. Name and daytime telephone number of person to contact in the United Kingdom

A.J. BRIDGE-BUTLER 020 7242 7680

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APPARATUS FOR USE IN PERFORMING TRANSFEMORAL OSTEOTOMY

This invention relates to an apparatus for use in performing transfemoral osteotomy. In this surgical technique the femur is exposed along a proximal-distal line, the soft tissue (skin, muscle) being folded back on each side to expose the bone. The proximal end of the femur is now opened as a "window" and a femoral prosthesis is inserted into the bone canal.

The technique requires careful pre-operative planning, usually from X-rays and it is possible to calculate in advance how far to cut the "window" so that the distal edge of the "window" end can become a datum base.

There are obvious difficulties in assessing the particular angular position of the prosthesis in the femoral canal and the exact location of the resectioning of the femur must be accurately judged. A further difficulty arises with regard to the placement of one or more retaining bolts towards the distal end of the stem of the prosthesis. These bolts or pins pass through the bone, the stem of the prosthesis and out through the other side of the bone thus anchoring the prosthesis in position. It is difficult for surgeons to judge the exact position to drill the holes in the bone to coincide with the holes in the implant and it is also necessary to select the correct angular position for the prosthesis and therefore the holes. It is also difficult to judge the exact distance down the femur for the holes to achieve the correct leg length of the correction.

The present invention is intended to overcome some of the difficulties referred to above and provide apparatus which provides a more accurate surgical technique.

According to the present invention, apparatus for use in performing transfemoral osteotomy surgery comprises a support element provided with a drill guide, means for securing the support element to a prosthesis to be implanted, and to a resectioned femur, and means for

adjusting the angular position of the drill guide in relation to the resectioned femur about a proximal-distal axis.

Thus, the apparatus can be used to accurately locate the angular position of the drill guide and the prosthesis (anteversion setting) which can be used to drill the holes to take the retaining bolt or bolts in the bone.

Preferably the support element includes means for connection to the proximal end of the femoral prosthesis.

Means can be provided to indicate the angular position of the drill guide relative to the resectioned femur.

Thus, after careful X-ray examination the precise anteversion setting can be decided and this can then be transferred to the apparatus thus ensuring the correct angular position.

The apparatus can also include means for adjusting the support element to accommodate alternative leg lengths. In order to do this means can be include to vary the proximal-distal position of the support element in relation to the prosthesis securing means.

Once again, the necessary dimensions and requirements can be taken from X-rays and preset on the apparatus.

With this arrangement the drill guide can be located at a predetermined proximal-distal position from the means for connection to the proximal end of the femoral prosthesis.

Means can be included for locating the drill guide in alternative proximal-distal positions on the support element thus the apparatus can be adapted for prostheses with holes in different positions and two or more drill guides can be provided.

The means for securing the support element to the resectioned femur is preferably in the form of an adjustable open jawed clamp adapted to partially surround the femur with which it is to be used.

Guide means can be included for locating the support element on the resectioned proximal end of the femur and these guide means can be carried on the femur securing means.

The support element can be in the form of an L-shaped frame, one arm of which carries the drill guide and the femur securing means and the other arm carrying the means for connection to the femoral prosthesis which is to be implanted.

With this arrangement the femur securing means can be connected to the L-shaped frame by a bracket which can be adjusted in proximal-distal directions on the frame and in relation to which the femur securing means can be angularly adjusted about a proximal-distal axis.

Apparatus as set forth above is described in GB-A-0027698.0 filed on 13 November 2000 and the present Application relates to improvements and alternative embodiments which can be employed.

In a preferred construction the bracket is readily removable from the L-shaped frame.

The femur securing means can include means for adjusting and clamping the securing device according to the femur diameter.

In another preferred embodiment the means for securing the support element to the resectioned femur includes a universal joint.

The invention can be performed in many ways but one embodiment will now be described by way of example and with reference to the accompanying drawings in which :

Figure 1 is a diagrammatic side view of a femur showing how it is cut for performing transfemoral osteotomy surgery;

Figure 2 is a diagrammatic perspective view showing how the "window" is formed in the femur for transfemoral osteotomy surgery;

Figure 3 is a diagrammatic isometric view of apparatus according to the invention;

Figure 4 is a part cross-sectional view of means for securing the support element of the apparatus shown in Figure 3 to a prosthesis to be implanted;

Figure 5 is a side elevation of a clamp device shown in Figure 3 for securing the support element to a resectioned femur;

Figure 6 is a front elevation of the clamp device shown in Figure 5;

Figure 7 is an isometric view of part of the support element;

Figure 8 is a partial side view of an alternative construction of the clamp device shown in Figures 5 and 6;

Figure 9 is an isometric view of the construction shown in Figure 8;

Figure 10 is an isometric view of the construction shown in Figure 9 partially dissembled;

Figure 11 is an end view of the device shown in Figure 3 incorporating the alternative constructions shown in Figures 7, 8, 9 and 10 and including visual indicator guides and with the support element in a first position;

Figure 12 is a similar view to Figure 11 with the support element in a second aligned position; and,

Figure 13 is an isometric view showing a rule guide which can be clamped into position to enable holes to be made through the bone and soft tissue T when it has been folded back into position on the femur.

Figures 1 and 2 show, in simplified form, transfemoral osteotomy surgery is performed. The soft tissue indicated by reference letter T in Figure 2 is exposed along a proximal/distal line indicated by chain line L in Figure 2. The soft tissue T is folded back on each side to expose the femur 6 and the bone is resected with three cuts along the same line L two side cuts M and with a transverse cut C. The proximal end of the femur is now opened, as shown in Figure 2, as a "window". From Figure 2 it will be seen that an upper quarter 48 is now laid on each side of the remaining part of the bone to expose the bone canal into which the prosthesis is to be inserted.

As shown in Figures 3 to 6 of the drawings apparatus according to the invention for performing transfemoral osteotomy surgery comprises a support element 1 provided with two drill guides 2, means 3 for securing the support element 1 to a prosthesis 4 which is to be implanted and means 5 for securing the support element 1 to a resectioned femur which is indicated by reference numeral 6. Adjustment means 7 are included for adjusting the angular position of the drill guides 2 in relation to the resectioned femur 6 about a proximal-distal axis.

The support element 1 is in the form of an L-shaped frame having a first arm 10 and a second arm 11. The first arm 10 carries the drill guides 2 and the femur securing means 5 and the second arm 11 carries the means 3 for connecting the support 1 to proximal end of the femoral prosthesis 4.

The femur securing means 5 (to be described below) is connected to the first arm 10 by an adjustable bracket 12 which can be adjusted in proximal-distal directions only in a slot 13 in the arm 10 and locked in position by a retaining nut 14, and the femur securing means 5 can be angularly adjusted in relation to the bracket 12 in a slot 15 provided on the bracket and locked in position by a nut 16. The nut 16 is carried on a screw threaded boss indicated by reference numeral 17 is carried on the femur securing means 5.

The means 3 for connecting the support element 1 to the femoral prosthesis which is to be implanted is shown in more detail in Figure 4 and comprises a sleeve 20 secured to the second arm 11 and in which is located a securing stud 21.

The proximal end 22 of the prosthesis 4 is provided with a screw threaded bore 23 in which a screw threaded portion 24 of the stud 21 can be located. The other end of the stud is held by a nut 25.

The distal end of the sleeve 20 is provided with a pair of opposed projecting keys 26 which engage in keyways 27 in the form of slots provided in an enlarged end portion of the bore 23.

Thus, it will be seen that the prosthesis 4 can be held in position on the arm 11 and is restrained against relative rotation by the keys 26 and keyways 27.

The means 5 for securing the support element to a resectioned femur 6 is most clearly shown in Figures 5 and 6 and comprises an open-jawed clamp device. This device has a main body portion 30 on which is located a movable clamping jaw 31. The upper part of the

clamping jaw 31 has a screw threaded bore 32 which houses a threaded member 33 one end of which carries an operating handle 34 and the other end of which is rotatably housed in the body 30. Thus, rotation of the handle 34 raises and lowers the clamp 31 which is also located by a retaining screw 35 which passes through a slot 136.

The lower end of the open jawed clamp is formed as a pair of curved tines 36 which are adapted to extend around the resectioned femur to which the device is to be clamped.

Guide means in the form of a disc 38 mounted on body 30 are provided, the disc projecting below the lower end 39 of the body 30.

The boss 17 is located in a slot 40 in the body 30 and held by a nut 37 but is free to move so that the position of the clamp adjusts itself in relation to the adjustment bracket 12 to alter the radial distance from the femur 6.

The drill guides 2 are carried on the arm 10 by a clamping plate 40 which is held in place by a screw threaded shaft 41 retained by a nut 42. The shaft 41 passes through one of a series of four openings 43 in the arm 1. As will be seen, once the guides have been fixed in position there is a predetermined distance from the guides to the means 3 for connecting the support element 1 to the femoral prosthesis 4. This distance can however be adjusted by using the alternative openings 43. The drill guides 2 are set for a position with respect to the given prosthesis so that they are fixed and aligned with the holes 44 in the prosthesis 4.

A typical drill bit 45 is shown in place in one of the drill guides 2 and its lower operative end 46 indicates how it has been drilled through the femur 6 passing through the existing holes 44 in the stem 47 and through the other side of the femur 6.

In Figure 3 the bone and soft tissue T, which has been folded back to provide the "window" and expose the femur 6, is indicated by broken lines 48.

To carry out the surgery relating to a transfemoral osteotomy the surgeon first ensures that appropriate X-rays have been taken so that he can consider the amount of bone which needs to be removed from the femur. Once having decided this the measurements are carefully taken for further use with the apparatus according to the invention.

The "window" is now opened to reveal the femur and the bone is cut appropriately to provide a proximal end C, indicated by reference numeral 49 in Figure 3. The clamp 5 is now located in position on the end of the femur by tucking it around the femoral end and ensuring that the guide disc 38 is close up against the severed end 49. The positioning is achieved with a rotative movement. Once in place the handle 34 is operated to close the clamp and retain it in place. The stem 47 of the prosthesis 4 is now inserted in the femoral canal and the frame in the form of the arms 10 and 11 is connected to it by means of the securing means 3.

The nut 14 is released to allow the bracket 12 to move in the slot 13 and so that it can be secured to the femur securing means 5 by the boss 17 and nut 16 through the slot 15. The release of the nut 16 allows the slot 15 to be placed on the boss 17 at the appropriate radial distance from the femur prior to subsequent tightening. It will be appreciated that the proximal-distal movement in the slot 13 accommodates the leg length adjustment. The ante/retroversion adjustment is now carried out by revolving the frame about the axis of the prosthesis 4 and the particular angle adjustment is set by tightening the nut 16. During this angular movement the prosthesis 4 which is securely attached to the support frame revolves with it as do the drill guides 2.

The proximal-distal positioning of the drill guides is set according to the pre-operative planning and they are now positioned by releasing the nut 42 so that they can be located in contact with the cortex of the femur and the nut suitably tightened.

The drill guides can now be used to produce the necessary holes through the bone to accept the required bolts or pins.

In the arrangement described above two drill guides are shown but only one or any other number can be utilised if required.

The apparatus can be simply removed by releasing the stud 21 in the prosthesis 4, releasing the nut 16 and removing the frame. The clamp 6 can be removed separately.

The "window" is now closed according to any known post-operative technique.

The above apparatus is disclosed in GB-A-0027698.0

Figure 7 shows an alternative construction in which the same reference numerals are used to indicate similar parts. In this arrangement the adjustable bracket 12 can be readily disconnected from the first arm 10 of the L-shaped frame. In this construction the nut 14 is shown as a hand nut and is carried on a boss 50 which has a bore 51 adapted to receive a spigot 52 provided on the end of the bracket 12. The boss 50 also carries a screw threaded locking nut 53 which can be advanced through a screw threaded bore (not shown) so that it engages against the spigot 52 where it is located in the bore 51 to clamp it in position. This construction enables disconnection of the assembly without having to unscrew the locking nut 14 thus enabling the leg length to be set without readjustment.

Figure 8, 9 and 10 show an alternative construction for the open jawed clamp device and the same reference numerals are used to indicate similar parts to those shown in Figures 5 and 6. In this construction however, the boss 17 is replaced by a bolt 60 which extends through the slot 40 and carries a spacer 61. One end 62 of the spacer is dished to accommodate a part-spherically shaped washer 63. A second part spherically-shaped washer 64 is also located on the screw 60 and one side of this is housed in a dished portion 65 of a nut 66.

The nut 66 has a circumferential groove 67 to accommodate resilient ring (not shown) which can act to retain a socket wrench during assembly. Each of the washers 64 and 63 also has a flat side which are located against the sides of the slot 15 on the bracket 12 when the whole construction is assembled together with the screw 60 passing through the slot 15.

With the nut 66 tightened the assembly is tightly clamped together but if the nut 66 is slackened the bracket 12 can align itself in three different directions by movement of the part spherical washers in the spacers 61 and 65. This enables three relative rotations, one of which is the anteversion setting and the other two rotations enable replacement of the stem in the femur if the clamp is ill positioned on it.

As the attachment of the clamp to the bracket 12 is also adjustable and can be clamped in position movement of the clamp in the direction of the arrows 68 on Figure 9 this enables the automatic adoption of the femur diameter and once set can be tightly adjusted to provide rigidity of the assembly.

Figure 11 shows how visual indicator guides can be provided. Thus, a visual indicator guide arm 70 is attached to the L-shaped frame 10 in the form of a rod which extends at 15° to the axis of the first arm 10. A second indicator guide 71 which is also in the form of a rod is attached at an angle normal to the longitudinal axis of the clamp main body portion 30.

Using the visual indicator guides the apparatus is placed in position with the clamp positioned perpendicular to the 90° knee flexion plane. This is the first position of the anteversion at 0° and this is shown in Figure 11. In Figure 12 the L-shaped frame 10 has been rotated until the visual indicator guides 70, 71 are parallel. In this position the frame 10 has been rotated through 15° in relation to the clamp 30. Thus, the neck axis is parallel to the axis of the frame 10 and the rotation of the frame has thus created an angle between the

clamp and the frame which is the anteversion angle. The exact angle of anteversion can be read from a scale indicated by reference numeral 72 provided on the bracket 12.

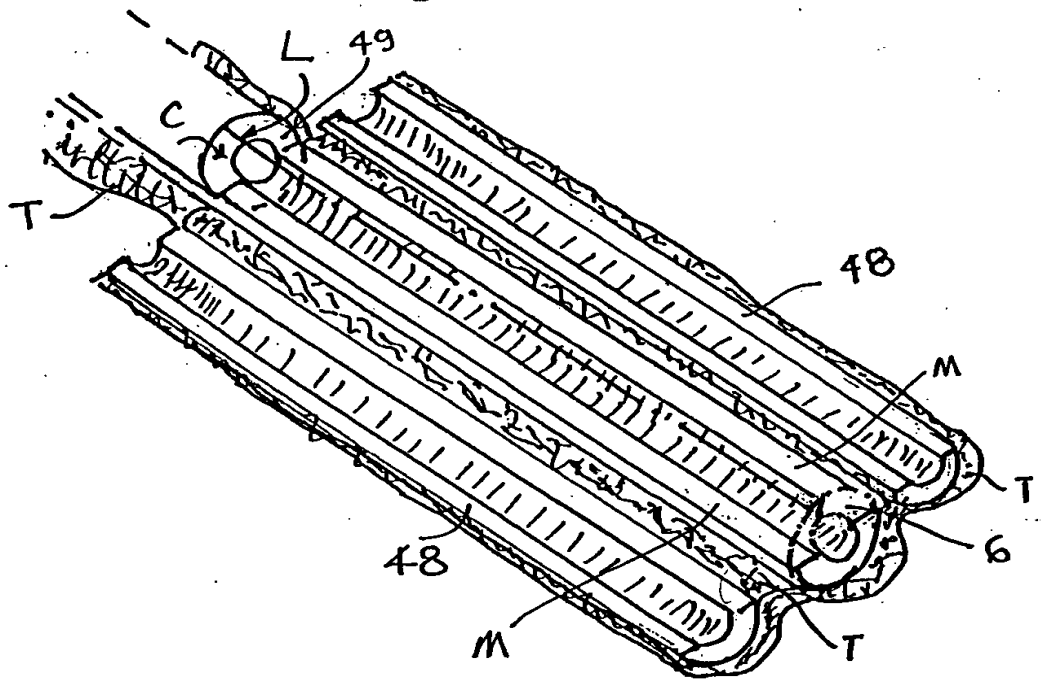
The standard value of anteversion is 15° and this can be used as a datum when setting up the apparatus.

When the "window" is closed it is necessary to fold the soft tissue and bone which has previously been folded back to provide the window back into position and locate it around the installed prosthesis. Figure 13 shows how a proximal drill guide 75 can be provided to guide drills through the folded back "flap" and to enable the drills to line up with pre-arranged holes 76 provided on the prosthesis 4. This device is in the form of an open jawed clamping block 77 which is provided with a tightening screw 78 which passes through a threaded bore (not shown) in the block to extend into the gap 79 provided between a lower clamping jaw 80 and an upper clamping jaw 81. The clamping block 77 carries an arm 82 which supports a pair of drill guides 83.

As will be seen from Figure 13 the prosthesis is provided with a series of openings 76. With the prosthesis in position in the support element 1 and held by the second arm 11 the clamping block is placed in position and the drill guides are aligned by the use of guide rods or drills 84. With the drill guides now aligned with the openings 76 the clamping screw 78 is tightened to lock the clamping block in position. The rods or drills 84 can now be removed, the "window" is closed and the drill guides employed to guide the drill or drills to make openings in the flap of bone and soft tissue 48. The openings can then be located by passing wire hoops through the openings and suitably locating them thus ensuring that the flap of material is held in place.

Apparatus as described and shown in Figures 8 to 13 can also be employed with the apparatus described in GB-A-0027700.4 filed on 13 November 2000.

Fig 2



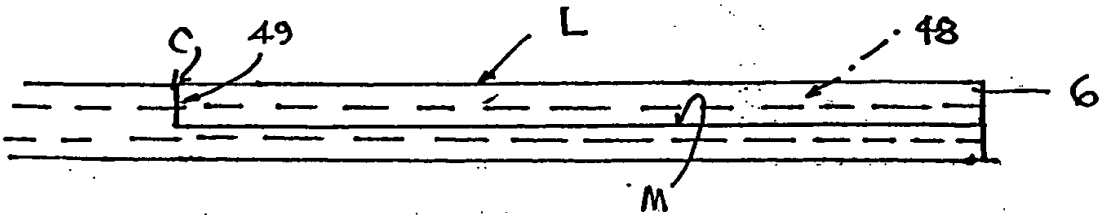


Fig 1

Fig 3

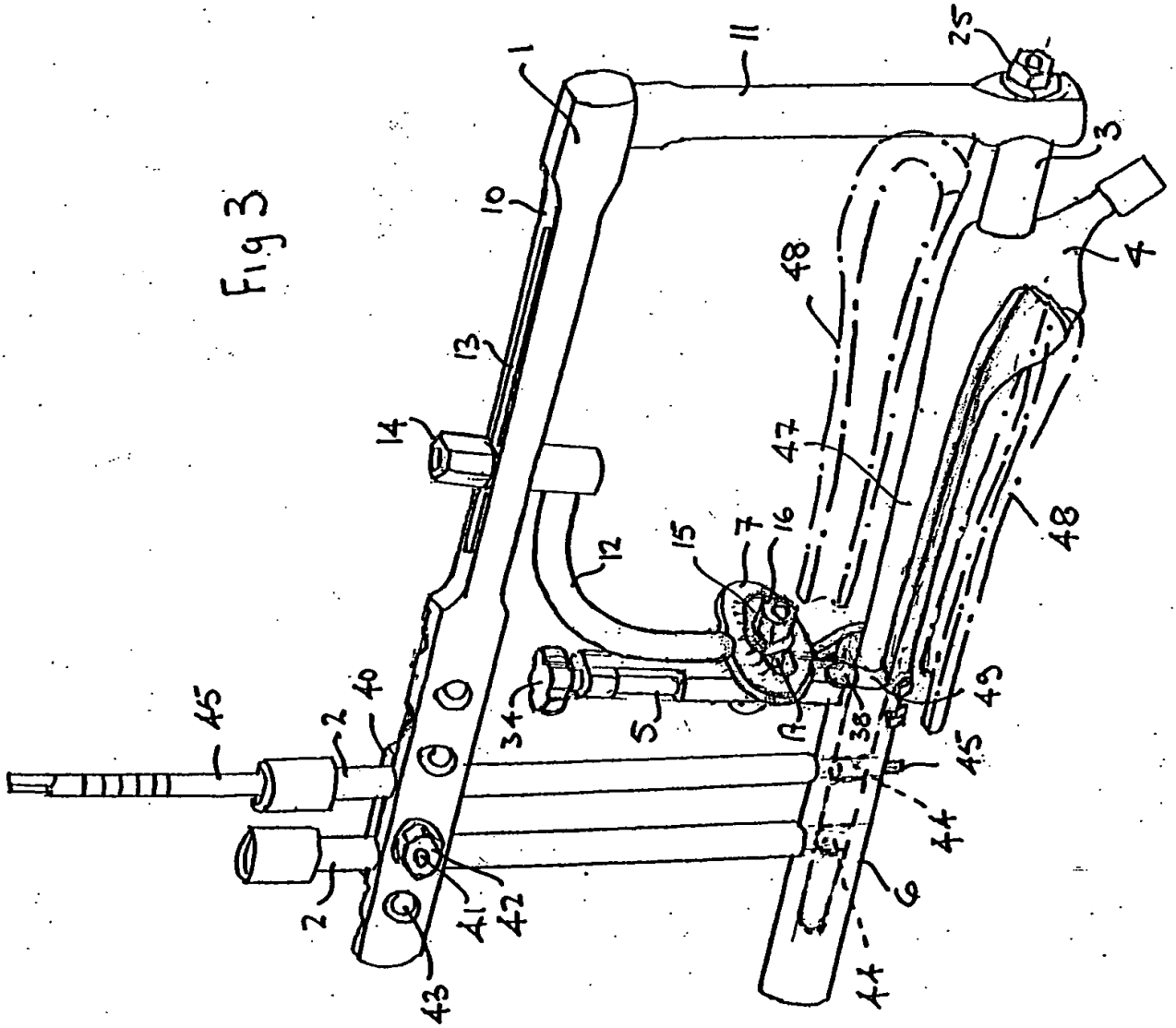

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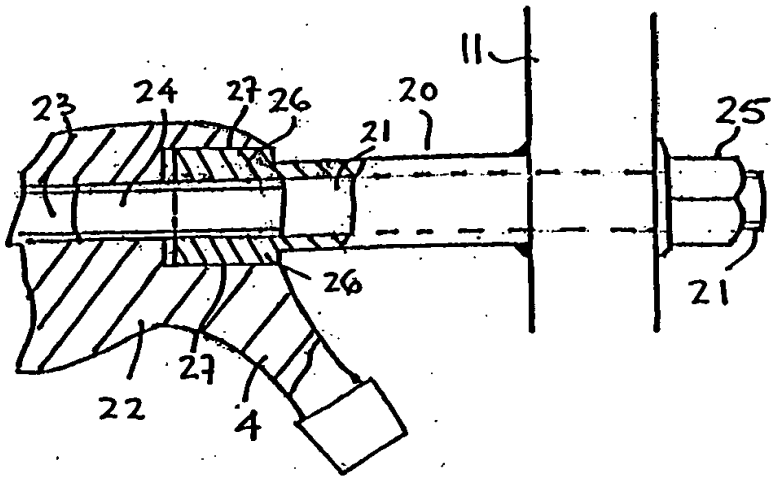
Fig 4



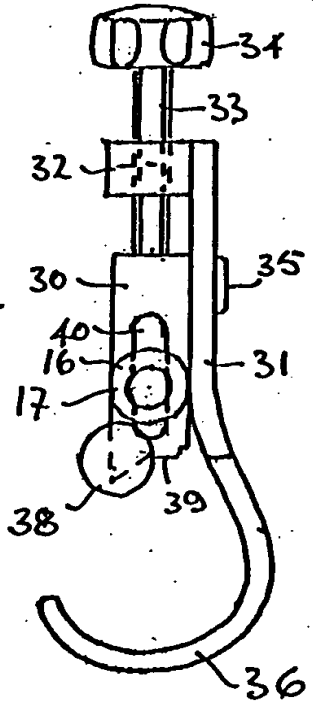


Fig 5

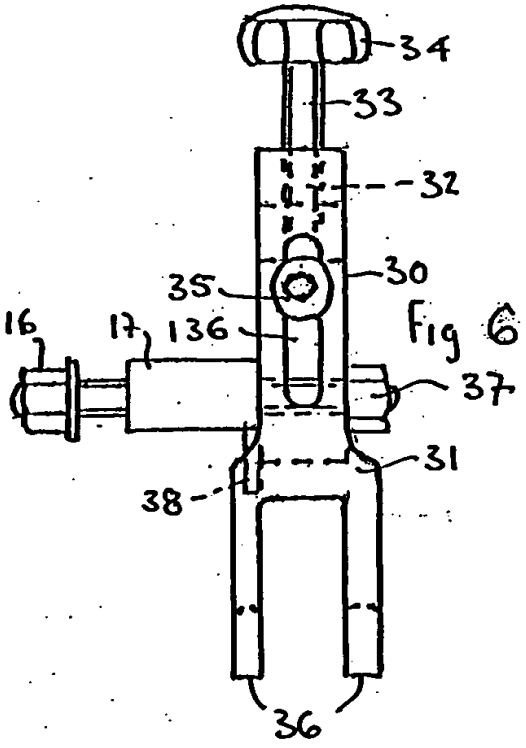


Fig 6

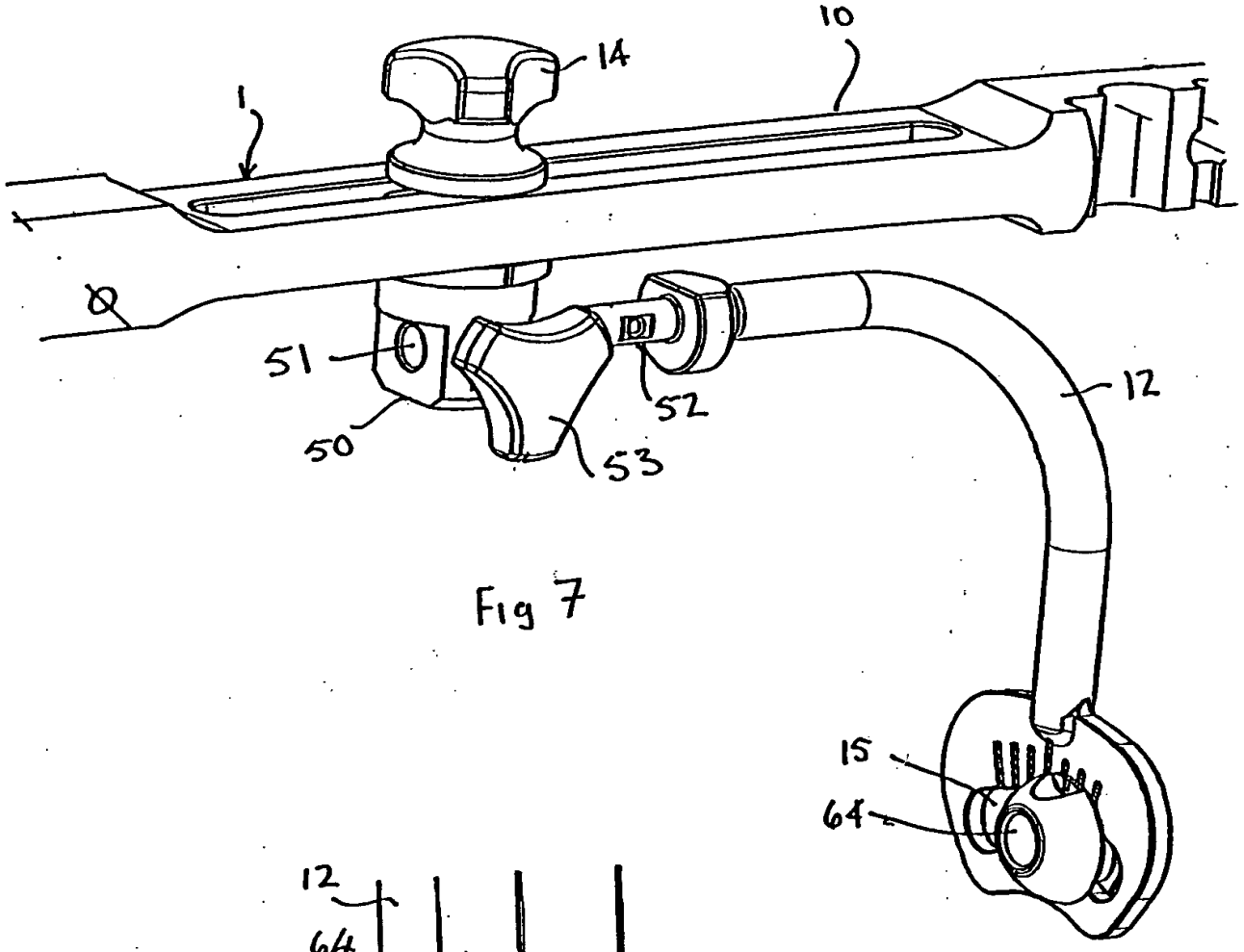


Fig 7

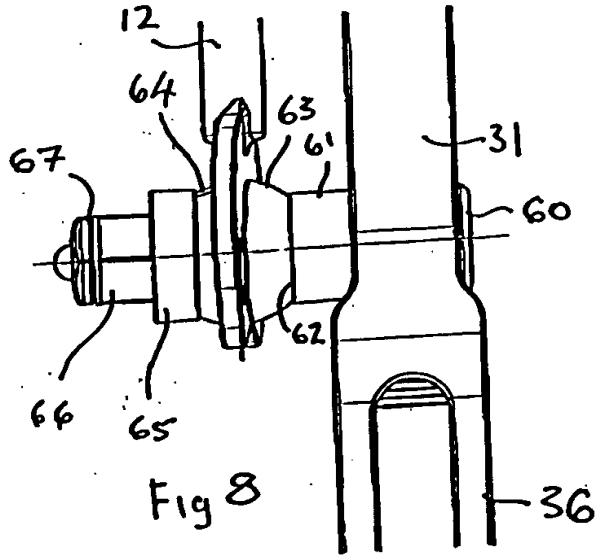


Fig 8

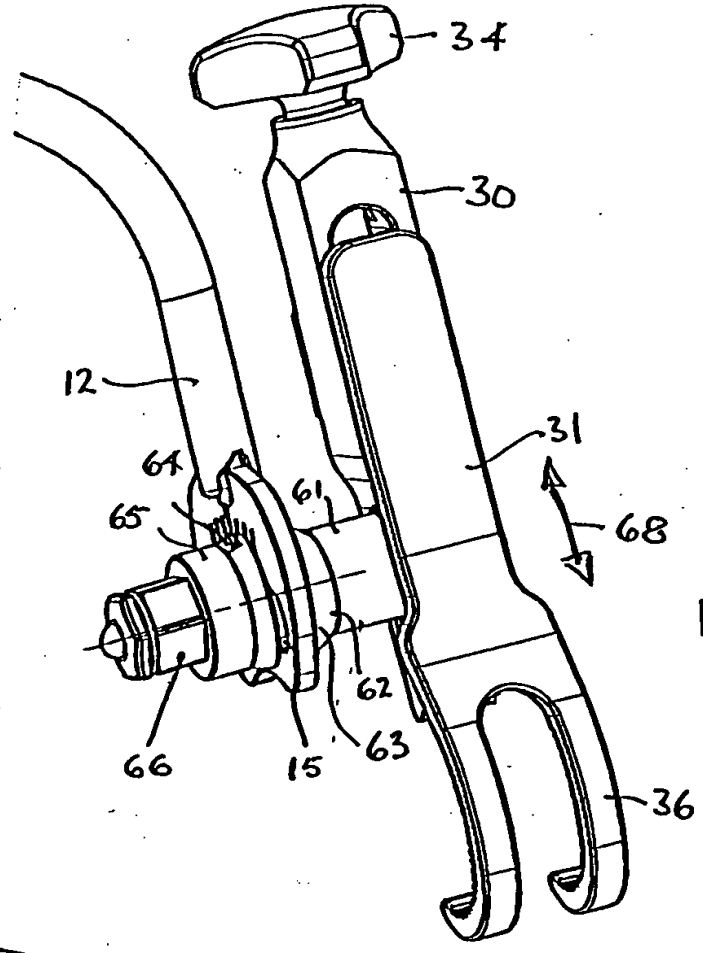


Fig 9

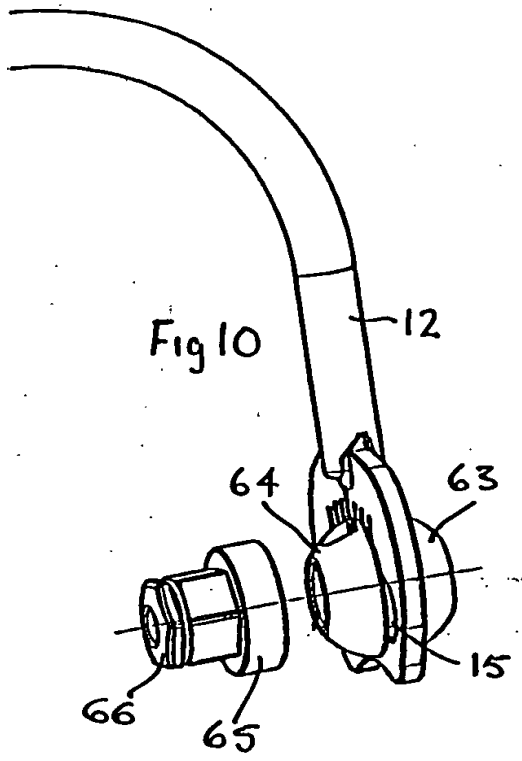


Fig 10

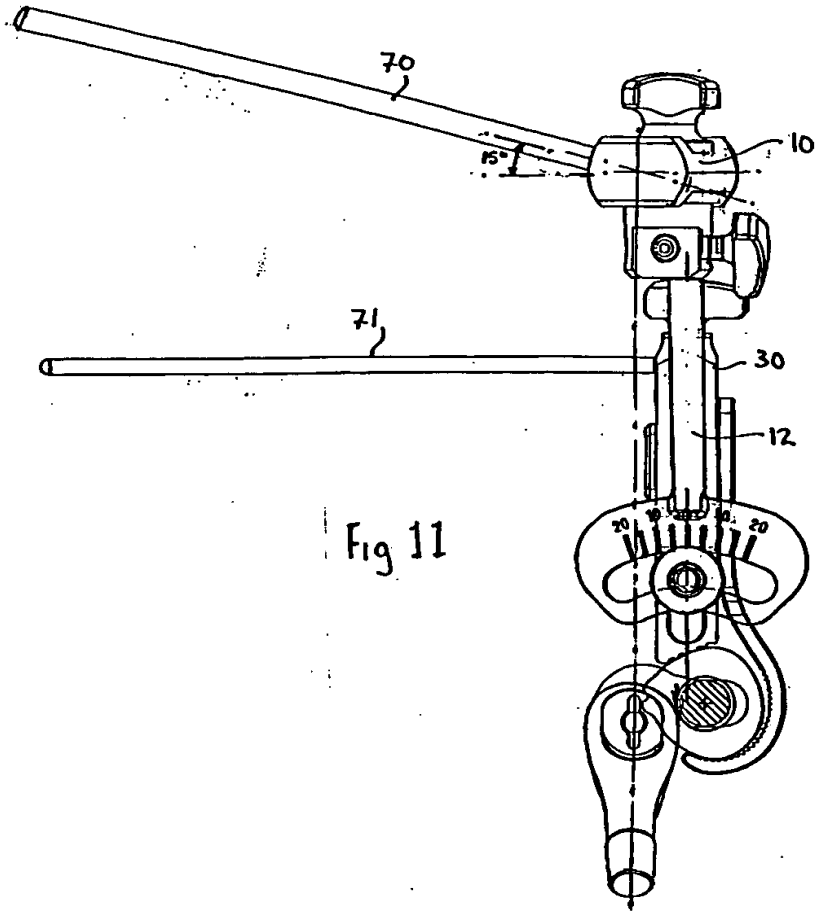


Fig 11

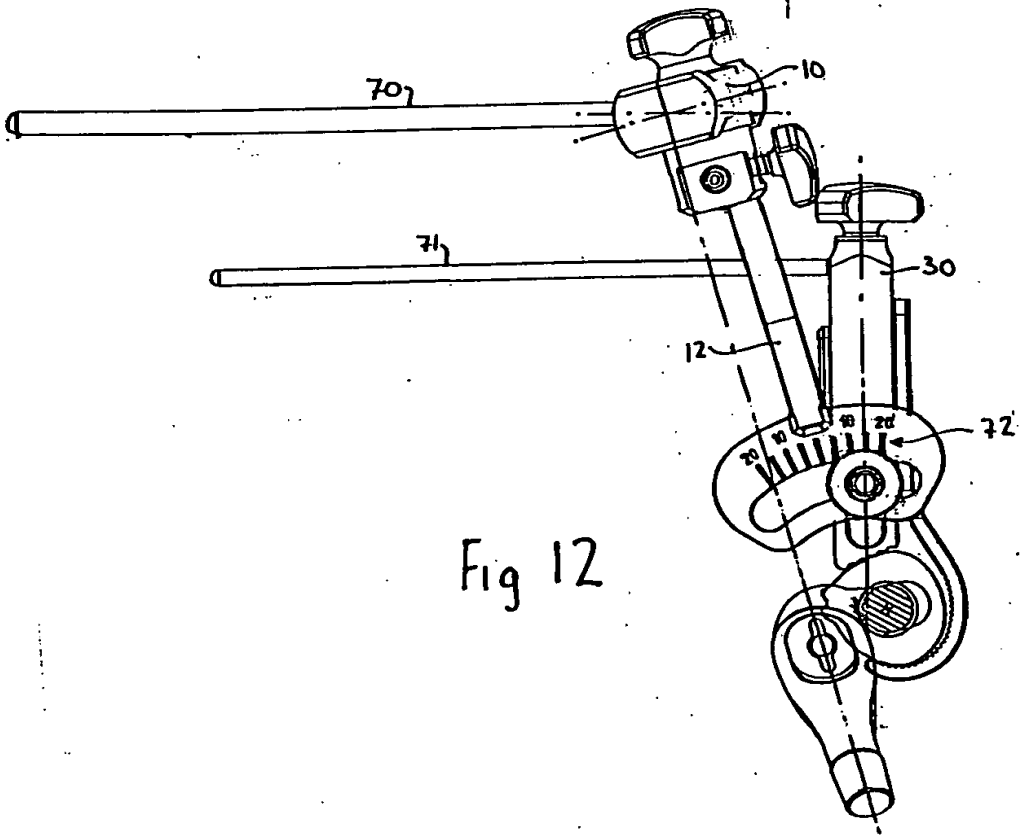


Fig 12

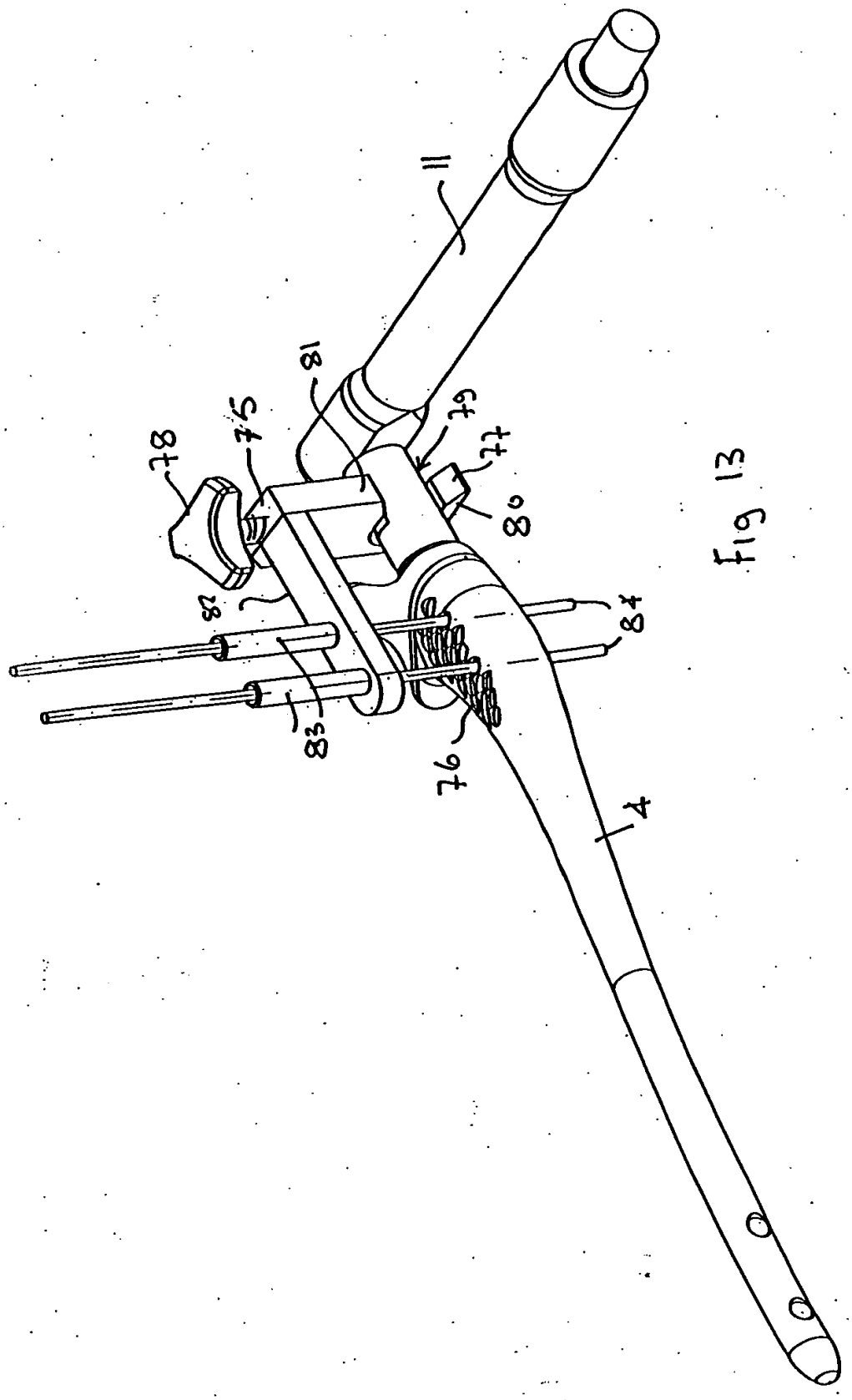


Fig 13